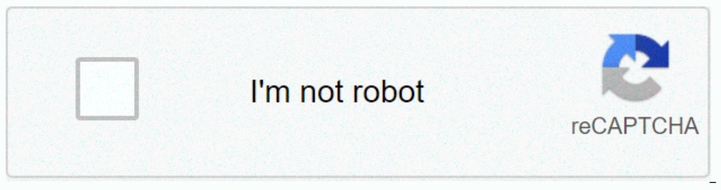

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Material safety data sheet validity

In this section: Prescription Drug User Fee Changes Content TableRecoduse and ResultsIn relation to adjustments to changes to activity, validation efforts include comparing PDUFA IV Workload Adjuster data with data from CDER and CBER for the following seven data items: 1) Labeling Attachments; 2) Annual Reports; 3) NDA/BLA Meetings Planned; 4) NDA/BLA Applications; 5) SPA's; 6) IND Meetings Planned and 7) IND Applications. Data provided by CDER and CBER included the number of applications for NDA/BLA and INDs for the PDUFA years between 2002 and 2008. CDER and CBER also provided activity factor counts for the five review activities mentioned above for the PDUFA years between 2002 and 2008. CDER and CBER time reporting data for FY 2006 and FY 2006 are considered outside the scope of this assessment due to the sensitive nature of the data. Data requests were sent to CDER and CBER to obtain counts associated with seven data items. The data was obtained from systems where information was stored by each center. Data validation efforts, PDUFA IV Workload Adjuster.ColumnData ElementData Validation1Submission Counts:- Labeling Attachments- Annual Reports- NDA/BLA Meetings Planned- NDA/BLA Applications- SPA-IND Meetings Planned- IND Applications CDER and CBER2ASubmission Counts:- Labeling Attachments- Annual Reports- NDA/BLA Meetings- NDA/BLA Applications- SPA's- IND Meetings Planned- IND Applications2bActivity Factor Data:- Labeling Attachments- Annual Reports- NDA/BLA Meetings Planned- SPA-IND Meetings 2a and 2bNot Applicable3 Derived from Columns 2a and 2bNot Applicable3 Columns Derived from 1 and 2cNot Applicable4Accescement Factors:- NDA/BLAs- Overridden against weight factors obtained from standard cost model. The Standard Cost model is outside the scope of this project, so no validation is performed on any of the Standard Cost Model data derived from Column 3 and 4Note ApplicableFigure 3 – Summary of Data Validation Efforts for the PDUFA IV Workload AdjusterThe data validation results for the new data feature are shown in the following tables (between Figure 4 and 10) and a description of the varients found is followed. Etiketleme TakviyeleriPDUFAYearCDERData[a]CBERData[b]TotalCDER & CBER[a] + [b] = [c]PDUFA IVWorkloadAdjuster[d]Varyans[c] - [d] = [e]PercentageDifference[e] / [c] = [f]2002761 74835815202.40%200377393866836303.46%20041,011701,0811,040413.79%20057765082678 7394.72%200688549934902323.43%20071,024531,0771,037403.71%200891248960914464.79%20071 Şekil 4 – Etiketleme Ekleri İçin Veri Doğrulama SonuçlarıPDUFAYearCDERData[a]CBERData[b]TotalCDER & CBER[a] + [b] = [c]PDUFA IVWorkloadAdjuster[d]Varyans[c] - [d] = [e]PercentageDifference[e] / [c] = 5 – Data Validation Results for Annual ReportsPDUFAYearCDERData[a]CBERData[b]TotalCDER & CBER[a] + [b] = [c]PDUFA IVWorkloadAdjuster[d]Variance[c] - [d] = [e]PercentageDifference[e] / [c] = [f]20023427441641600.00%20034128049249200.00%200436655421399225.23%200532842370346246.49%200632858386372143.63%200728544329316133.95%200823862300296641.33%Figure 6 – Data Validation Results for NDA/BLA Meetings ScheduledNDA/BLA Meetings ScheduledPDUFAYearCDERData[a]CBERData[b]TotalCDER & CBER[a] + [b] = [c]PDUFA IVWorkloadAdjuster[d]Variance[c] - [d] = [e]PercentageDifference[e] / [c] =

[f]20023427441641600.00%20034128049249200.00%200436655421399225.23%200532842370346246.49%200632858386372143.63%200728544329316133.95%20082386230029641.33%Figure 7 – Data Validation Results for NDA/BLA ApplicationsNDA/BLA ApplicationsPDUFAYearCDERData[a]CBERData[b]TotalCDER & CBER[a] + [b] = [c]PDUFA IVWorkloadAdjuster[d]Variance[c] - [d] = [e]PercentageDifference[e] / [c] = [f]2002909999900.00%2003113812111564.96%20041296135138-3-2.22%20051059114117-3-2.63%20061284132133-1-0.76%20071091512411686.45%2008141414513874.83Figure 8 – Data Validation Results for SPAs IND Meetings ScheduledPDUFAYearCDERData[a]CBERData[b]TotalCDER & CBER[a] + [b] = [c]PDUFA IVWorkloadAdjuster[d]Variance[c] - [d] = [e]PercentageDifference[e] / [c] = [f]20027582831,0411,04010.10%20031,0163161,3321,338-6-0.45%20041,3381961,5341,537-3-0.20%20051,6491961,8451,819261.41%20061,7332001,9331,942-9-0.47%20071,6701911,8611,86100.00%20081,5332101,7431,767-24-1.38%Figure 9 – Data Validation Results for IND Meetings ScheduledActive INDsPDUFAYearCDERData[a]CBERData[b]TotalCDER & CBER[a] + [b] = [c]PDUFA IVWorkloadAdjuster[d]Varyans[c] - [d] = [e]PercentageDifference[e] / [c] = [f]20023,6591,3204,9794,982-3-0.06%20033,7 641,3525,1165,123-7-0.14%20044,7668885,6545,661-7-0,12%20055,0478435,8905,900-10-0.17%20065,3858296,2146,252-38-0,61%20075,1688245,9925,8431492.49%20085,5218646,, 3855,8325538.66%Şekil 10 – IND Uygulamaları için Veri Doğrulama Sonuçları FDA'ya göre, PDUFA IV İş Yükü Ayarlayıcısı'nda kullanılan değerler ile FDA tarafından doğrulama amacıyla bize sağlanan değerler arasındaki tutarsızlıklar kaynak veritabanlarının zaman içinde farklı noktalarda sorgulanmasına kaynaklanmıştır. Varients may occur in the data due to the dynamic structure of the source data and continuous updates to the data. The properties and attributes of a particular application can be set as required during the review, and all updates to that application are made accordingly within the system. Examples that affect shipping counts and complexity factors include: Data Entry Latency: It can take several days from the purchase of an application to its entry into the database. If the database is queried by a user during this window, query results may underestimate the total number of submissions for the application type in the n. For example, if three new applications are received on June 30 (PDUFA year cut-off date Workload Seter) can be captured in a query that runs immediately after this date. FDA analysts try to reduce this risk by delaying the database query until the last possible point. Data Update Delay: Because individual reference submissions contain many areas where they must be marked correctly, these critical flags may not be known until a significant review of the submission package is performed; This process can take up to two months (for example, categorizeing an NDA as a New Molecular Entity (NME) or non-NME, and also as important as it takes whether it contains clinical data). Even after adding flags, the FDA may have some time earlier to update the delivery in the system due to competing priorities. If the database is queried while these submissions are being processed, the query results may not represent the last number of submissions until all entries have been updated. Note that data update latency will affect NDA/BLA subsethies, but will not have a significant impact on the overall count. FDA Data Reporting Method: Under the current methodology for collecting and reporting data used in the PDUFA workload adjuster, data is collected for every 12-month period ended June 30 and recorded in mid-July. To make periods from previous years comparable to subsequent years, amounts from previous years are not re-specified - they always remain constant to the values reported for each year. Naturally, the reassessment of these values for our evaluation purposes produced slightly different values than the values usually recorded first and repeated here without changes for the year concerned. Human Input Errors: Errors may occur by the user when the application is entered or updated into the system. Multiple levels of quality assurance are frequently performed, but resource constraints make it difficult from time to time. New Data Systems: Over the past few years, a new consolidated database for the FDA's CDER submission types has moved correctly, namely, Document Archiving, Reporting, and Regulatory Monitoring System (DARRTS). CDER IND applications were moved to DARRTS in 2007 and CDER NDA applications were planned for migration in 2009. This new database responsively responsively to automated updates to data based on clearly defined business rules that reduce the need for manual data entry (helping to update data entry and delays and human input errors). This database also includes a robust trace backtrack feature that will document changes made to the database. However, switching to a new database can cause several problems that can affect the stability of data: When data is passed from one system to another, there is a possibility that data will be lost or modified during migration. The FDA implements comprehensive quality assurance measures to protect data integrity during migration. Any new structure also requires new queries that will provide the same results from the old database. The FDA faced difficulties in creating comparable queries using the new Business Object query interface. Training is provided to support the development of queries capable of navigating the intricacies of questioned data. Some variability is expected in the query results until all data migration issues are addressed. Using the data received to support our verification effort, we simulated adjustments to review activities for the PDUFA IV Workload Adjuster (see columns 4-10 2,, 3, and 4) as new encodings. Based on the results of the simulations, we believe that data varients do not have a significant impact on adjustments for changes in review activities. However, we believe the FDA can implement additional procedures to reduce these data varients (see observations below). Approach and Results Back to The Top